Performance Issues of the 3M 8710 Respirator

A. Introduction

In 1962, 3M introduced the 8500 as a low-cost throw away nuisance dust mask. 3M promoted it as effective against airborne particles of limestone, marble, sandstone, and other non-toxic dusts. However, these mineral dusts cannot be considered "non-toxic." The filter efficiency for the 8500 was low and it could not pass the approval test. To expand the market share, 3M developed the 8710. In 1972, it was approved jointly by the Mine Safety and Health Administration (MSHA) and the National Institute for Occupational Safety and Health (NIOSH) as a single use respirator. It is a formed cup shape half-mask, equipped with a filter element integrated to the facepiece. It also has two yellow color elastic headband straps. 3M promoted its use as a low-cost, throwaway, and maintenance- free respirator to other industries, such as manufacturing and mining.

B. Definitions

Aerodynamic diameter: The diameter of a unit density sphere having the same settling velocity as the particle in question, of whatever shape or density. Particles can be measured by using different parameters, such as shape, volume, settling velocity, etc. The aerodynamic diameter corrects for all of these parameters. It is the correct way to describe particle diameters.

Air-purifying respirator: A respirator that removes contaminants from the ambient air before the wearer breathes the air. There are two types of air-purifying elements. The filter is used to remove particulates, such as dust, mist, fume, or smoke. The sorbent is used to remove gases or vapors.

Disposable respirator: A type of air-purifying respirator, generally designed to protect against airborne particulate matter. It usually does not contain an elastomeric facepiece, but instead has an all fabric construction. Almost all disposable respirators have a half-mask design. Maintenance such as cleaning, sanitation, or repair, is not intended for this type of respirator. The name used for the disposable respirator keeps changing. It was originally called a "single use" respirator in the 1970s. The name was changed to "disposable" in the 1980s. It was further changed to "maintenance-free" in the 1990s. However, the most appropriate term for this class of respirators should be "filtering facepiece" since this term reflects its design. Also, this term has been recognized by the OSHA and the European Union.

Facepiece: The portion of a respirator that covers the wearer's nose and mouth in a quarter mask (above the chin), or half-mask (under the chin) facepiece or that covers the nose, mouth and eyes in a full facepiece. It is designed to make a gas-tight or particle-tight fit with the face and includes the head straps, exhalation valve(s), and connections for an air-purifying device or respirable gas source, or both.

Fit factor: The ratio of the concentration of the airborne test agent in the air of the ambient atmosphere to the concentration of the airborne test agent in the air inside the facepiece, in the breathing zone of the respirator wearer. OSHA requires a minimum passing fit factor of 100 for the half-mask respirator.

Filtering facepiece (dust mask): A negative pressure particulate respirator with a filter as an integral part of the facepiece or with the entire facepiece composed of filtering medium. It is same as the disposable respirator.

Exhibit 2

High-efficiency particulate air filter: A particulate filter which has passed the DOP certification test. It is called HEPA filter. It has an efficiency of 99.97% against any particulate air contaminant.

Micron: A commonly used metric unit for measuring particle size. It is one millionth of a meter. It is also called micrometer (μm). One inch equals to 25,400 microns.

Monodisperse aerosol: There is very little variation in the particle size distribution (less than 20%) of the aerosol.

Negative pressure/positive pressure sealing test: A respirator facepiece sealing test. It is also called fit check, user seal test, or wearer seal test.

Permissible exposure limit (PEL): The regulatory agency enforced time-weighted average or ceiling concentration of a contaminant that shall not be exceeded. For example, in the 1970s the OSHA PEL for asbestos was 2 fibers per cubic centimeters of air (fibers/cc), and the MSHA specifies an exposure limit of 2 milligram per cubic meter (mg/m^3) for respirable coal dust.

Polydisperse aerosol: The particle size of the aerosol has a variation of at least two or more orders of magnitude. For example, the oil mist aerosol that is commonly used for performing quantitative fit testing has a mean particle size of 0.6 micron. The particle size varies between 0.1 and 6 microns.

Projected diameter: The particle diameter visually measured through an optical microscope. For example, the projected diameter of the silica dust used for filter certifying test has a projected diameter of 0.4 to 0.6 micrometer. The mass median aerodynamic diameter is around 2 micrometers.

Qualitative fit testing (QLFT): An assessment of the adequacy of the facepiece of a specific make and model respirator to seal on a particular person's face by determining whether or not the person detects the penetration of an airborne test agent into the facepiece by sensing odor, irritation, or taste of the test agent. The qualitative fit test is a pass/fail type test. Any detection of the airborne test agent by the respirator wearer means that the facepiece has failed to achieve a satisfactory seal on the wearer's face.

Quantitative tit testing (QNFT): A respirator fit test that uses instrumentation to measure the ratio of the concentration of an airborne test agent in the air of the ambient atmosphere and the concentration of the airborne test agent in the air inside the facepiece in the breathing zone of the wearer.

Respirator: A device worn by a person for protection against inhalation of a harmful atmosphere.

Respiratory-inlet covering: All respirators are equipped with a respiratory-inlet covering. It serves as a barrier against the harmful atmosphere and provides a means of connecting the respirator wearer's respiratory system to an air-purifying device or source of respirable air, or to both. There are two general types of respiratory-inlet coverings. One type is called "tight-fitting" and the other type is called "loose-fitting."

Single use respirator: A filtering facepiece respirator, which is a class of approved particulate filter respirators. It is also called a disposable or maintenance free respirator by 3M.

Workplace Protection Factor (WPF): The results of measuring the performance of a respirator worn by a person performing work on a job site. The WPF is the ratio of the measured average concentration of the air contaminant present in the workplace atmosphere to the measured average concentration of the contaminant in the air inside the facepiece of the respirator, and in the breathing zone of the respirator wearer.

C. Respirator Classification

Air purifying respirators can be classified by the inlet covering, operating mode, and type of contaminant removed. The inlet covering serves as a barrier against harmful atmosphere and provides a connection to an air-purifying element. There are two common types of respirator inlet coverings: "tight fitting" and "loose fitting." The loose fitting respirator inlet covering may cover a portion of the head, the entire head, the head and neck, the head and shoulders, the upper trunk of the body, or the whole body.

A tight fitting respirator inlet covering has a facepiece that covers the respirator wearer's nose, mouth, chin, or face. The facepiece is designed to provide a gas tight or particulate tight seal on the respirator wearer's face. It is usually made of elastomeric materials, such as neoprene or silicone rubber. A facepiece that covers the nose and mouth, with the lower sealing surface resting between the mouth and chin, is called a quarter-mask facepiece. A facepiece that covers the nose and mouth, with the lower sealing surface under the chin, is called a half- mask facepiece. A facepiece that covers the eye, nose and mouth and extends from the hairline to below the chin is called a full facepiece respirator. The full facepiece in general provides the best and most reliable seal on the respirator wearer's face. The half-mask facepiece generally provides a better and more stable seal on the wearer's face than the quarter-mask respirator. A respirator can be designed for protection against particulate, gases or vapors exposure. A filter in a disk or a cartridge is used for particulate protection. A cartridge is used to protect against various types of gases or vapors, such as organic vapor, acid gas, or amine. A combination cartridge provides protection against particulate, gas, or vapor exposure.

Another type of respirator inlet covering is called a filtering facepiece. It is a fabric respirator with a particulate filter as an integral part of the facepiece, or with the entire facepiece composed of the filtering medium. This type of respirator is also called a disposable respirator. The 3M 8710 or 8210 is an example of this type of respirator.

Straps are used to provide a tight and stable seal on the respirator. The full facepiece usually has five adjustable headband straps that provide the best seal and stability on the face. The half-mask elastomeric facepiece respirator usually has dual loop adjustable fabric head straps. A head cradle is provides additional stability on the head. However, the elastic head strap of the filtering facepiece, such as the 3M 8710, is not adjustable. It provides a less stable fit, and an inadequate seal on the face compare to elastomeric facepieces with adjustable headband straps.

The operating mode of a respirator consists of positive or negative pressure. It is also called a powered or non-powered mode. In the negative pressure mode, the contaminated air is pulling through the air-purifying element and the faceseal when the respirator wearer inhales. When the respirator wearer exhales, the exhaled breath is expelled from the respirator by passing out the respirator through an exhalation valve or by passing through the air-purifying filter element.

The powered air-purifying respirator (PAPR) utilizes a battery-operated blower, which is carried by the respirator wearer. The blower passes contaminated air through the air-purifying element, which

removes contaminants from the air. During the inhalation, the contaminated air may leak through the respirator faceseal of a non-powered respirator. Since the blower creates a positive pressure, it generally prevents the leakage of contaminated air through the inlet covering of the respirator. A full facepiece PAPR equipped with a single HEPA filter cartridge is commonly used for asbestos abatement.

D. Respirator Testing and Certification Regulations

Before the enactment of the Occupational Safety and Health Act (OSH Act, 1970), respirators were tested and approved by the Bureau of Mines (BM) under the provisions of Part 11 of Title 30 of the Code of Federal Regulations (30 CFR 11) [1]. The BM approval was a voluntary program. The OSH Act created the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH). OSHA enforces the respirator use regulation, which is prescribed in Part 1910.134 of Title 29 of the Code of Federal Regulations (29 CFR 1910.134). NIOSH took over the respirator testing and approval regulations under the provisions of the Mine Safety and Health Act. Both OSHA and MSHA require that all respirators must be approved jointly by MSHA and NIOSH under the provisions prescribed in 30 CFR 11. There are several subparts listed in 30 CFR 11. The requirements for testing particulate filter respirators are prescribed in Subpart K. In 1995, MSHA transferred the approval authority of non-mine use respirators to NIOSH. Respirators would be approved under the provisions of 42 CFR 84 and NIOSH became the sole approving authority. NIOSH has also developed a new filter testing method under the provisions of 42 CFR 84, that is vastly different from the testing methods specified in 30 CFR 11.

There are four types of particulate filter testing methods prescribed in Subpart K of 30 CFR 11:

Silica dust (sand), silica mist, lead fume, and the di-octyl phthalate (DOP) or di-ethyhexyl phthalate (DEHP) tests. The silica dust test is required for the approval of all filters. The test silica dust particles have a projected particle size of 0.4 to 0.6 micrometer (measured by an optical microscope). The dust is generated inside a dust chamber at a concentration between 50 and 60 milligrams per cubic meter. The respirator or filter is mounted outside the chamber and dust penetrating through the filter is collected on the back-up filter at a continuous air flow of 32 liters per minute. The respirator facepiece to the wearer's face contacting surfaces are sealed on a mold to measure only the filter leakage. The test period is 90 minutes. In order to pass the test, the filter must have a minimum efficiency of 99%. The single use respirator is also tested against silica dust. This test is performed on a breathing machine at an intermittent air flow of 24 respirations per minute at a minute volume of 40 liters per minute. The maximum filter penetration for the silica dust test is 1%. The requirement for the silica dust test is listed in §11.140-4.

The performance test requirement for silica mist is similar to the test for silica dust (§ 11.140-7), except that an aqueous suspension of silica at 20 to 25 milligram per cubic meter replaces the silica dust, and the test period is 312 minutes. The silica mist test is designed for mine operations that use water mist for dust control. The silica dust and silica mist tests are required in the combination approval of dust/mist filters. Since the silica particle concentration in the silica mist is lower than the silica dust, a filter that passes the silica dust test would also pass the silica mist test.

The lead fume test is performed inside a test chamber with freshly generated lead oxide fumes at a concentration from 15 to 20 milligrams of lead per cubic meter of air. Other test conditions, including air flow, are the same as the silica dust test except that the test period is 312 minutes for non-powered, and 4 hours for powered respirators. The maximum allowable filter penetration is 1% ((§ 11.140-6).

The di-2-ethylhexyl phthalate (DEHP or DOP) test is only performed on high-efficiency particulate air (HEPA) filters (§ 11.140-11). The filter is challenged with a heat generated monodisperse oil mist of DEHP having a size of 0.3 micrometer at a concentration of 100 milligrams per cubic meter. The maximum allowable penetration is 0.03 % after a test period of 5 to 10 seconds. The HEPA filter cartridge is the only respirator component listed in Subpart K of 30 CFR 11 for which the DOP test is performed on each cartridge manufactured. The term "monodisperse" means that the particles have little variation in size.

To ensure that the respirator is relatively comfortable to wear, there is also a breathing resistance requirement (§ 11.140-9 (b)). The maximum permissible breathing resistance for the dust/mist filter respirator during inhalation and exhalation is 50 and 20 mm water pressure, respectively. The maximum permissible breathing resistance for the single-use respirator during inhalation and exhalation is 15 mm water pressure. The maximum inhalation resistance for asbestos dust is 18mm during initial inhalation, and 25mm at final inhalation. The exhalation resistance is still 15mm. The lower resistance may be designed for asbestos workers who already have impaired lung capacity. The 3M 8710 respirator had failed this test on numerous times.

There is a facepiece tightness test (fit test) required to determine whether the respirator would provide an adequate fit to the user (§11.140 -1 and 2). The test agent is isoamyl acetate (banana oil), which is a vapor that smells like a banana. This test can be conducted on commonly used elastomeric facepiece respirators equipped with interchangeable cartridges for protection against particulate, gas, or vapors exposure. The test cannot be conducted on single use (filtering facepiece) respirators such as the 3M 8710, since the vapor would penetrate the filter readily and cause a failure. The 3M 8710 was exempted from this test.

There is a quality assurance program that requires NIOSH to determine whether approved respirators on the market still meet the certification test requirements. NIOSH staff members also visit respirator manufacturers to conduct on-site quality control audits.

There are three classes of approved dust respirators: single use, reusable filter, and replaceable filter. The single use respirator certification is a new addition to the Bureau of Mines respirator certification regulations. The single use respirator is specifically approved for protection against pneumoconiosis and fibrosis producing dusts and mists, including but not limited to dust containing aluminum, asbestos, coal, flour, iron ore, and free silica. However, it has not been tested against asbestos fibers in certification tests. The 3M 8710 was originally approved as a single use respirator. Later, it was approved as a respirator equipped with a replaceable dust/mist filter.

The respirator is approved as an assembly that includes the filter, facepiece, breathing tube or other components. Each approved respirator carries an approval number. The particulate respirator approved by MSHA/NIOSH has an approval number of TC- 21C-XXX, where TC means testing and certification, and 21C is the testing schedule. The 3M 8710 was approved on May 24, 1972 with an approval number of TC-21C-132. The approval number for the 3M 8210 is TC-84A-0007.

E. Defects

Two major sources of respirator leakage are the filter and the faceseal. To ensure effective protection, these leakages must be minimized. The filter must remove the respirable dust. The facepiece must provide a proper seal on the face. However, the 3M 8710 respirator has not met the above requirements. Workers who used the 3M 8710 respirator was not informed of the defects of this respirator, and they believed the 3M 8710 would provide effective protection against inhalation of asbestos fibers when in fact, did not. A false sense of security led to the disabling lung disease.

1. Design

In the 1970s, the quantitative fit tests conducted by Hyatt of the Los Alamos Scientific Laboratory (LASL) indicated that faces of the U. S. workers vary greatly in size and shape. A single size facepiece would not fit [2]. In the early 1980s, Survivair introduced three sizes of elastomeric half-masks. These silicone rubber facepieces are more pliable than the natural rubber facepieces. All other manufacturers, including 3M, have introduced three sizes of half-masks. To further improve the stability of the half-mask respirator, the Norton Company added a head cradle. Almost every manufacturer has adopted this design. However, there was only one size of the 3M 8710.

Most elastomeric facepiece half-mask respirators have adjustable fabric head straps and a four-point suspension to provide a tight fit. The 3M 8710 has two non-adjustable rubber head straps. 3M had introduced adjustable fabric head straps on other models, e.g., 9920. The 8710 still has non-adjustable head straps.

Mr. John Masaitis from the U.S. Steel Corp., a major user of respirators, cast a negative vote for the ANSI Z88.2-1992 standard with the following statements: "*Observation of the disposable respirators in the workplace shows these devices to be unable to maintain an adequate facepiece to face seal after repeated donning and removal. The assigned protection should be lower, possibly half of that of the masks with more substantial made facepieces*." [3]

After repeated failures to pass the required silica dust test for the single use respirator, 3M obtained an approval as a respirator equipped a replaceable dust/mist filter, since that the test was easier to pass. There are requirements specified in the 30 CFR 11 with which the 3M 8710 was not complied:

§11.134 (b) Each respirator shall be equipped with a substantial, durable container.
§ 11.135(a) half-mask facepiece and full facepiece shall be designed and constructed to fit persons with various facial shapes and sizes either: (1) By providing more than one facepiece size, or (2) by proving one facepiece size which will fit varying facial shapes and sizes.
§ 11.138 (b) Facepiece head harness shall be adjustable, and replaceable.

However, the 3M 8710 does not have adjustable and replaceable head straps, has only one facepiece size, and did not provide a container for each respirator.

2. Filter Performance

The first Bureau of Mines particulate filter certification test was developed in 1930s. This dust filter test required a very high concentration (50 milligrams per cubic meter) of silica dust, and the integrated penetration was the only measurement taken at the end of the 90-minute test. The integrated measurement method would permit approval of less efficient filters because it permitted the penetration of fine particles to occur until a cake was built up on the respirator filter surface that improved its efficiency. The cake decreases the penetration of particles, and the filter can then meet the approval filter penetration requirement. The respirator wearers would be continuously exposed to the toxic dust until a cake was built up on the filter to improve its efficiency. The size of the silica dust particles is measured by an optical microscope. It shows a project diameter of 0.6 micron. The aerodynamic diameter is commonly used to express particle size and it corrects for variations in particle shape, density and other parameters of measurements. When converted to the aerodynamic diameter, the aerodynamic diameter of the silica dust is around 2 microns [4]. The correct size of the silica dust is not submicron size, and 3M misrepresented this fact to the respirator user.

There are several mechanisms that attract particles to the filters. Inertia impaction and sedimentation are used to attract large particles. Smaller particles are attracted by direct interception. Diffusion force is used to attract very small particles. Filters that rely on these mechanisms to attract particles are called “mechanical filters.” The electrostatic charge is another method of collecting particles on the filter. The advantage of electrical enhancement is that it improves collection efficiency without a substantial increase in breathing resistance. It is called electrostatic filter. However, the electrical enhancement is unstable. It can be neutralized by high temperature and humidity, or exposure to chemicals. Most approved filters use a combination of mechanical and electrostatic forces to attract particles. Once the electrical charges built up on the filter have been compromised, the remaining efficiency due to mechanical forces would not be sufficient for the filter to provide protection. Most approved dust/mist filters are electrostatic filters.

3. Fit Testing

There are three sources of respirator leakage: filter, faceseal, and exhalation valve. Since the filter of 3M 8710 also serves as an exhalation valve, the sources of leakage become the filter and the faceseal. There are two types of fit testing methods available: quantitative and qualitative. A quantitative fitting test (QNFT) assesses the leakage between the faceseal of the respirator and the wearer’s face by using instrumentation to measure the ratio of the concentration of an airborne test agent in the ambient air and in the inside of the respirator. The ratio of the ambient and in-mask concentration of the test agent is called the "fit factor," or “protection factor.” For a half-mask, the minimum OSHA required passing fit factor is 100. The challenge is a submicron sodium chloride or di-ethylhexyl phthalate (DEHP or DOP). To isolate the filter leakage, a HEPA filter element (0.03% penetration) is required for this test. The submicron aerosol would cause excessive filter leakage on the 3M 8710 respirator, and this method cannot be applied to this respirator.

A qualitative fitting test (QLFT) is an assessment of the adequacy of the facepiece-to-face seal by determining whether or not the person detects the test agent by sensing odor, irritation, or taste. The qualitative fit test is a pass/fail type test. Any detection of the test agent by the respirator wearer

means that the facepiece has failed to achieve a satisfactory seal on the wearer's face. It is a “pass or fail” test, and cannot determine which facepiece provided less leakage.

Since 1970s, there have been two commonly used qualitative fit testing (QLFT) methods: the isoamyl acetate (banana oil) and the irritant fume. Isoamyl acetate (IAA) has a pleasant and easily detectable odor, with a low odor threshold. It had been used for performing fit testing before the development of the quantitative fit testing method. The simplest version of this test involves saturating a piece of cotton or cloth with the liquid IAA and passing it close to the face and the respirator sealing surface. This method does not work on the 3M 8710 respirator since the IAA vapor would readily pass through the filter element to fail the test.

A commercially available smoke tube used for checking ventilation systems produces an irritant fume. These tubes are filled with either stannic chloride or titanium tetrachloride impregnated pumice stone. The irritating fume consists of hydrochloric acid absorbed on small solid particles. The irritant fume is directed at the facepiece seal, and leakage is detected by the user's involuntary coughing or sneezing caused by irritation of the respiratory tract. Both QLFT methods and the QNFT method have been listed in the ANSI Z88.2-1980 standard as commonly used fit testing methods. However, the 3M 8710 respirator cannot be fit tested using any methods listed in the 1980 ANSI Z88.2 standard because the submicron particles used in these methods would penetrate the respirator filter and cause excessive leakage to void the test[5].

The Los Alamos Scientific Laboratories conducted QNFT for various respirators equipped with approved dust filters [6.] The test was performed on a 16 test subject anthropometric test panel. The test aerosol was sodium chloride having a MMAD of 0.6 ± 0.1 µm. Respirators selected for testing included AO 2090, MSA Dustfoe 66 and77, and 3M 8710. The test subjects performed the following seven exercises: normal breathing, deep breathing, turning head from side to side, and moving head up and down, talking, normal smiling, and coughing. Another series of five exercises do not include smiling and coughing. The average allowable panel penetration is 5% and maximum allowable penetration is 10 %. The test results are shown in the following table:

Respirator	Initial filter pen, %		All 7 Exercises		Basic 5 exercises		No. failing performance criteria
	Range	AV.	Panel range	Panel Avg.	Panel range	Panel avg.	
MSA Dustfoe 66	2.5 – 6.0	3.4	2.9 -11.0	6.3	2.5-9,0	5.5	9
MSA Dustfoe 77	1.7 – 3.0	2.5	4.0 -31.0	11.1	4.0-26.0	8.5	11
AO R2090	10 – 8.5	4.6	4.0-30.0	13.5	4.0-28.0	12.3	13
3M 8710			6.0-16.9	12.5	6.0-17.4	12.5	16

It appears that all tested respirators failed the performance criteria. The 3M 8710 has the worst performance. None of the tested respirators provided adequate protection to the user. The current allowable average penetration for passing a fit testing is 1% for the half-mask and 2% for the quarter mask.

The final OSHA standard on inorganic lead published in the late 1970s required that only HEPA filters be used on air-purifying respirators and also required that QNFT be performed on negative pressure respirators[7]. Since the 3M 8710 was not equipped with a HEPA filter element, and the 8710 could not

be quantitatively fit tested because the excessive filter leakage would fail the test, 3M filed a petition with OSHA for an administrative stay and a reconsideration of the HEPA filter and QNFT requirements in the lead standard. OSHA held a hearing to determine whether qualitative fit testing could be accepted as an alternative to QNFT. Three proposed QLFT methods were introduced at the proposal for comments. The testing agents for these methods were: isoamyl acetate developed by the Du Pont Company, the irritant fume developed by the American Iron and Steel Institute (AISI), and sodium saccharin developed by 3M. Both isoamyl acetate and irritant fume have been used widely as test agents for QLFT. Du Pont and AISI refined these methods.

The saccharin fit test uses a person's sense of taste to detect leakage into the respirator. The person being tested must be able to detect a weak solution of sodium saccharin. This is determined by spraying a weak solution of saccharin into a small hood placed over the head. Next, while the person is wearing a respirator, the test hood is placed over the test subject's shoulder, and a stronger saccharin solution (~100 times stronger) is sprayed into the hood when the test subject is performing the required exercises that simulate the worker movements in the workplace. If the test subject does not detect saccharin, the fit test is passed and the person who passes the test is assumed to have a fit factor of 100. In November 1982, the sodium saccharin, irritant smoke, and the isoamyl acetate QLFT methods were accepted by OSHA as an alternate to the QNFT method.[8] This means that prior to 1983, 3M knowingly sold the 8710 in violation of the fit testing requirements specified in the OSHA respiratory protection standard.

In 1991, NIOSH stated that sodium saccharin was a suspected carcinogen and the Agency did not recommend the use of sodium saccharin as a fit testing agent[9]. 3M used Bitrex (denatorium benzoate) as a replacement for saccharin. Except for the replacement of saccharin, there is no change to this QLFT method. The sodium saccharin fit testing method received the most criticism during the hearing and after OSHA adopted this method. 3M claims that there is a 100 to 1 relationship between the low saccharin concentration during the sensitivity test and the high concentration of sodium saccharin inside the test enclosure. This corresponds to a fit factor of 100 when the test subject passes the fit test. However, there is no independent test to verify the 100 to 1 airborne ratio between the sensitivity test and the test hood concentrations. Also, there is no independent study to verify the sodium saccharin concentration inside the test hood during the test.

The data submitted by 3M to OSHA during the lead standard hearing indicate that using an electronic microscope to measure the "dry" saccharin aerosol particles collected on an electron microscope grid result in a count geometric mean particle size of 2.0 - 2.15 microns, with 99% of the particles being smaller than 7.0 microns. Since the respirator wearer's exhaled breath remains inside the 3M test hood, the humidity inside could be very high. Due to the high humidity, the saccharin mist exiting from the nozzle may not reduce in size, and may even increase in size. The large particles may not penetrate the faceseal of the 3M 8710.

The saccharin aerosol, which is introduced into the testing hood, is generated from a more concentrated saccharin solution by a nebulizer. In order to maintain the required concentration of saccharin inside the hood, intermittent squeezes of the nebulizer are needed to establish the claimed concentration. The number of squeezes is the same as that established during the sensitivity test. The force exerted by the hand can affect the delivery rate of sodium saccharin to the test enclosure. No independent validation data exists to indicate that there is no variation of concentration when different forces are exerted on the nebulizer by different test conductors, or on the same conductor over different time periods.

After the amended lead standard hearing, OSHA asked the Los Alamos National Laboratory to conduct a study on the effectiveness of the sodium saccharin QLFT protocol developed by the 3M Company.[10] The purpose of this study was to determine whether the saccharin method would reject poor fits that occur when the respirator wearer with an inadequate fit is not rejected by the QLFT. This statistical analysis is often called "false negative" or "Beta" error. An inadequate fit is defined as having a measured fit factor (FF) less than 100. The test results indicate a Beta statistic of 0.04. It corresponds to a Beta error of 0.08. This means that 8 out of 100 test subjects with inadequate fits (with fit factors less than 100) would not be rejected by the saccharin QLFT method. This error is too high for protection against a toxic mineral dust such as asbestos.

McKay and others at the University of Cincinnati conducted a study to determine whether the test subject could detect the taste of sodium saccharin or Bitrex when a fixed leak was introduced. The QNFT fit factors ranged from 96 to >20,000 without a leak, and 22 to 160 when fixed leaks were induced.[11] Twenty-four of 26 test subjects had fit factors <100 (92%) when a fixed leak was present. All tests subjects correctly detected Bitrex with fixed leaks. Nine of 26 test subjects (35%) were not able to detect saccharin in the presence of a known fixed leak, even though the average fit factor of the test subjects was 77 (100 is required to pass the test). When the two test subjects with fit factors >100 were excluded, only 16 of 24 respirator wearers were able to detect saccharin with fixed leaks. It should be noted that the Bitrex concentration was 40% more than the method prescribed by OSHA.

Another University of Cincinnati QLFT study used the standard Bitrex concentration specified in the OSHA method to determine the sensitivity to Bitrex.[12] The test results indicated that only 23% of participants were able to taste the Bitrex test solution through a fixed leaking exhalation valve retainer with a mean fit factor of 89, and a range of 71 to 96. The results reflect a dramatic 77% of false negatives (accepting an inadequate fit) with induced leaks and fit factors less than 100.

It is less likely that a respirator such as the 3M 8710, which has only one size of facepiece, would fit individuals having a variety of facial features. However, 3M has not mentioned the shortcomings of a single size in the 8710 user instructions. The Industrial Safety Equipment Association (ISEA), a trade group of respirator manufacturers, also cast doubt on the adequacy of the sodium saccharin QLFT method [13].

4. Fit Check (User Seal Test)

The OSHA respirator standard has two requirements on fit testing and fit check (user seal test). The fit testing requirement is prescribed in 1910.134 (e) (5). It states that "*For the safe use of any respirator, it is essential that the user be properly instructed in its selection, use and maintenance . . . Training shall provide the men an opportunity to handle the respirator, have it fitted properly, test its facepiece-to-face seal, wear it in normal air for a long familiarity period, and, finally, to wear it in a test atmosphere*."

The respirator fit check requirement is prescribed in 1910.134 (e) (5) (i). It states that: "*Every respirator wearer shall receive fitting instructions including demonstrations and practice in how the respirator should be worn, how to adjust it, and how to determine if it fits properly . . . To assure proper protection, the facepiece fit shall be checked by the wearer each time he puts on the respirator.*

The American National Standard Institute (ANSI) has issued a standard on respiratory protection. The Practice for Respiratory Protection (ANSI Z88.2-1980) has specified the following procedures for performing fit check [5]:

A7.2 Negative Pressure Sealing Test. *A negative-air-pressure respirator sealing test can be used on air-purifying respirators equipped with tight fitting respiratory- inlet coverings and on atmosphere supplying respirators equipped with tight fitting inlet coverings and breathing tubes which can be squeezed or blocked at the inlet to prevent the passage of air.* ***This test may be difficult or impossible to carry out on valveless respirators.*** *The inlet openings of the respirator's canister(s), cartridge(s), or filter(s) is closed off by covering with the palm of the hand(s), or by squeezing a breathing tube or blocking its inlet so that it will not allow the passage of air. Then the wearer inhales gently and holds breath for at least 10 seconds. If a facepiece collapses slightly and no inward leakage of air into the facepiece is detected, it can be reasonably assured that the fit of the respirator to the wearer is satisfactory.*

A7.3 Positive Pressure Sealing Test. *A positive-air-pressure respirator sealing test can be used on air-purifying respirators equipped with tight fitting respiratory-inlet coverings which contain both inhalation and exhalation valves.* ***This test may be difficult or impossible to carry out on valveless respirators.*** *The exhalation valve or the breathing tube, or both is closed off then the wearer exhales gently. The fit of the respirator is considered satisfactory if a slight positive pressure can be built up inside the facepiece without the detection of any outward leakage of air between the sealing surface of the respirator and the wearer's face.*

Donald P. Wilmes represented 3M on the ANSI Z88.2 Subcommittee that developed the ANZI Z88.2 – 1980 and 1992. He did not object to the negative and positive sealing test shortcoming statements associated with the 3M 8710 respirator.

To ensure proper fit, both the positive pressure and the negative pressure tests should be performed. The ANSI specified positive pressure and negative pressure fit check methods do not work with the 3M 8710 because of is valveless design. Both methods require the wearer to use their hand(s) to block off the inhalation valve or the exhalation valve of the respirator. Since the whole filter area of the 3M 8710 is the inhalation valve and exhalation valve, it is difficult or impossible to block off the whole filter to conduct the required fit check. 3M developed a positive pressure fit check (PPFC). It requires the user to cup the filter area and exhale *forcefully*. Since the hands cannot block off the whole filter area, this procedure is not effective. Also, forced fit creates an unrealistic mask sealing force with resulting low leakage.[14]

It is less likely that fixed length, non-adjustable headband straps, in regard to length would provide adequate faceseal to workers. Persons with large faces may find that the headband straps are so tight that they distort the shape of the respirator, which causes leakage of air contaminant between the face and the faceseal of the respirator. For a worker who has small face, the headband straps of the 3M 8710 would not have the sufficient tension to properly seal the facepiece to the face. Also, this construction would not meet the certification requirement of section 138a of 30 CFR 11 which requires that all respirator facepieces be equipped with head harnesses (head bands) designed and constructed to provide adequate tension during use and an even distribution of pressure over the entire area in contact with the face.

The revision of OSHA's cotton dust standard limited the use of filtering facepieces to an exposure limit of 5 times the PEL or an assigned protection factor (APF) of 5 [15]. 3M filed a petition to stay this

requirement. OSHA conducted a review of the 3M proposed positive pressure fit check (PPFC) method. 3M claimed that the test date indicated that the 8710 wearers who passed the test can achieve an APF of 10. OSHA reviewed the test data and found that a high percentage of improperly fitted 3M 8710 wearers passed the test but could not achieve an APF of 10.

After OSHA denied 3M's petition, 3M filed a lawsuit on this issue. The U.S. Court of Appeals ruled against 3M. The Court's decision states "*For the disposable respirator, the entire filter surface is intended to permit air intake. The worker's hands cannot effectively block intended air intake . . . Also, workers are not able to check reliably for proper fit*."[16] 3M did not file an appeal.

3M claimed that its fit check method was accepted by NIOSH. However, NIOSH stated that the Institute has never evaluated the effectiveness of the fit check procedure proposed by 3M. [17]

The fit check is the last step ensuring protection before the wearer enters the hazardous atmosphere. If an effective facepiece fit check cannot be performed on a respirator, the plaintiff could be subject to the inhalation of toxic dust without knowing it.

F. Workplace Protection Factor Studies

The workplace study is a method to evaluate the respirator performance during use, and it is expressed as the workplace protection factor (WPF). The WPF is a ratio between the ambient concentration (Co) and the in-mask concentration of the air contaminant (Ci). In the 1980s, the Du Pont Company submitted an asbestos workplace study to OSHA.[18] This study was conducted in response to the revised OSHA asbestos standard that required the use of HEPA filters and prohibited the use of any disposable respirator (3M 8710) even when it is equipped with a HEPA filter element (3M 9940).

The DuPont asbestos WPF study involved with the removal of asbestos fireproofing and insulation from piping. Copious water sprays were used to wet the asbestos to minimize exposure. The study compares the performance of disposable respirators and elastomeric half-mask respirators equipped with dust/mist filter, fume filter, and high-efficiency particulate air filters (required by OSHA). A high performance self-contained breathing apparatus (SCBA), which is used for firefighting, was also included for comparison.

The OSHA asbestos standard is expressed as fibers per centimeter of air (cc). The asbestos samples were collected on a membrane filter and counts the number of fibers over certain areas of the filter by an optical microscope. The OSHA asbestos standard requires counting to stop at 100 fields or 100 fibers, whichever comes first. Instead of stopping asbestos counting after 100 fields were counted, the DuPont study increased the counting fields d to 500 fields.

The test results are shown in the following table:

Table 1. DuPont Asbestos WPF Study Test results

Respirator	# of measurements	WPF range	WPF GM (GSD)	5% WPF*

3M 8710 (D)	18	7.4 – 3200	310 (5.3)	20
3M 9910 (D)	14	94 – 5600	580 (4.2)	55
AO R 1050 (D)	7	9.7 – 970	52 (4.2)	5
MSA & Survivair DFM (H)	17	15 – 4200	240 (6.3)	12
North 7700 HEPA (H)	14	12 – 7900	94 (3.0)	16
MSA & Survivair HEPA (H)	14	12 – 3100	250 (6.9)	11
Scott SCBA	2		620	

Note: Disposable respirator (D), half-mask elastomeric facepiece respirator (H) (Geometric mean (GM), Geometric Standard Deviation (GSD), 5% WPF, the WPF is expressed at a 95% confidence limit.

Asbestos Counting

The fiber concentration (C) is calculated by the following formula:

$$C = \frac{(E)(Ac)}{V\ (10^3)} \quad \text{fibers /c.c.} \qquad (1)$$

Ac = 385 $mm^{2.}$ filter area
V = air sampling volume in liters.

$$E = \frac{F/\ N_f - (B/N_b)}{A_f} \quad \text{fibers /mm}^2 \qquad (2)$$

F = total fiber count.
N_f = number of fields in submission sample.
B = mean field blank count.
N_b = number of fields in blank sample.
A_f = 0.00785 mm^2 for a properly calibrated Walton-Beckett graticule.

Source: OSHA Asbestos standard (29 CFR 1910.1001).

The WPF is a ratio between the ambient (Co) and in-mask concentrations.

$$WPF = Co/\ Ci$$

The study concluded that there was no statistical difference between the workplace protection offered by disposable respirators, such as the 3M 8710 or 9910, and the elastomeric facepiece respirators. All offered protection factors reliably above 10. The flat- fold AO respirator reliably offered a protection

factor above 5. The AO R-1050 is made of fibrous materials. Fibers released during use are counted as asbestos fibers that reduce the WPF values. Du Pont also concluded that "use of higher efficiency filters did not appear to improve the workplace protection factors of the elastomeric respirators. "

Both OSHA and NIOSH asbestos fiber counting methods require that counting stops when 100 fields or 100 fibers are counted, whichever occurs first. The fiber concentration (C) is affected by the number of counting fields (N_f). The higher the counting fields, the lower the value of E, and the value of C is lower. The ambient samples are counted in less than 100 fields. However, the in-mask samples are counted in at least 500 fields. The higher counting fields make the E lower. The in-mask fiber concentration (fiber/cc) becomes lower and the WPF value becomes higher.

Since a high concentration of water mist was sprayed over the insulation materials, the water droplets may have engulfed the asbestos fibers, making them too large to penetrate the faceseal. It is likely that very few fibers containing water droplets would have penetrate the faceseal of the respirator, so very few fibers would have been present when counting stopped at 100 fields for the in-mask samples. The higher fiber counting fields would have yielded more fibers, it also artificially increased the WPF value of the respirator.

Most samples reported high WPF values that are associated with an in-mask fiber count of less than 10 after counting 500 fields. The results are subject to high variation when more fibers are counted. In one set of the Survivair respirator sample, it reported a WPF value of 7,860. Only one fiber was found in the in-mask sample after counting 500 fields. The ambient fiber count was 174.5. If one more fiber was counted in the in-mask sample, the WPF would be reduced to 3,930. The WPF for the highly protective SCBA is 620, which is a little better than the 3M 870 of 310. Since large asbestos fiber containing water droplets do not penetrate the respirator faceseal, it makes the disposable respirators, such as the 3M 8710, perform better than the multi-size more pliable silicone rubber elastomeric half-mask respirators

In 1987, NIOSH proposed a revision of the respirator test and certification regulations (42 CFR 84). It proposed that respirators could only be certified after achieving a required workplace protection factor (WPF) in workplace testing. Respirator manufacturers and other parties opposed this requirement. In 1991, NIOSH sponsored a public meeting to address this issue.[19] The three-day technical conference addressed many problems and deficiencies associated with workplace testing. The representative from 3M made a presentation and made the following conclusions:

"*I would say that we do not know what these results mean. All we are doing now is working on methodology and doing research. We do not know what the test results really mean. So in conclusion, workplace protection factor studies we think can be useful in evaluating performance of respirators in the workplace. But the accuracy and reproducibility needed for a valid certification test is not currently achievable in this type of testing. Whether or not it will ever achievable is a question you might ask.* ***I would think for what we know the chances are it will not be achievable. It is not possible for us to standardize test protocols, to standardize sample collection, sample analysis, data analyses, and data interpretation in the manner that would adequately address unresolved technical issues***."

NIOSH retained Harry Ettinger from the Los Alamos National Laboratory to critique the conference. Mr. Ettinger made the following statements in his report:

Based on these technical problems the overwhelming opinion of meeting attendees was negative regarding the use of field testing as part of the certification process. They believed that:

1. It was not possible to identify a representative workplace.
2. There was no standard test protocol.
3. Field testing would introduce: uncontrollable test conditions; a high level of uncertainty; and a large number of poorly defined variables.
4. There was insufficient information to implement a test procedure of this type into a formal certification program.
5. Field testing to determine WPF was in a research stage of development.
6. The validity of extrapolating the results of any study to general use situations is in question.
7. The validity of extrapolating test results between different work situations is in question.

Another consultant retained by NIOSH to critique the conference, Dr. William Hinds from the University of California at Los Angeles, made the following comments:

"*There is great intrinsic variability in the measurement of WPFs because of the nature of the quantities being measured. This variability exists in addition to the variability of the quantity being measured, namely respirator performance, which is primarily associated with filter penetration and facial seal leakage. The source of contaminant in the workplace is variable with time and will often depend on quantities such as, production rate, process temperature and pressure. Airborne concentrations are intrinsically variable because they depend on air motion, air mixing, and worker movement in a complex and currently unknown way. There is substantial variation in the performance of aerosol filters even between filters from the same lot from the same manufacturer. Finally there is the human variability. People breathe differently, move differently, and generally behave differently while doing same job. These and other factors result in WPFs having a broad lognormal or other non-normal distribution, which complicates the statistical analysis of these data.*

Much of the variability cited above for workplace testing can be reduced by simulated workplace testing under controlled and reproducible conditions. In simulated workplace testing it is relatively easy to maintain test agent concentration (and size distribution in the case of a test aerosol) constant over lime and uniform throughout the test chamber. Test subject's tasks and motion can be standardized. To conduct meaningful workplace testing of respirators, testing needs to be standardized. This provides a level playing field for all manufacturers and allows the regulator and the user to interpret the results and make comparisons. ***Standardized tests would prevent manufacturers from shopping around for a workplace that will provide test conditions that are favorable to their product****. These needs are best met by controlled and reproducible simulated workplace testing."*

In spite of the problems associated with the workplace protection factors, 3M continued to conduct WPF studies on the 3M respirators. 3M has not asked the ANSI Z88 respiratory protection committee to develop a standardized test protocol to perform workplace protection factor testing. Since there is no

standardized test protocol, 3M is free to select the workplace that would yield the desired results. Most 3M workplace studies were performed in workplaces containing large particles [20]. Since large particles may not penetrate the respirator faceseal, high values of WPF are commonly reported in 3M presentations at the industrial hygiene conferences and in industrial hygiene publications. In some WPF studies the 3M 8710 performed equal to or better than the elastomeric facepiece respirators, even when QNFT test results clearly indicate that the elastomeric facepiece respirators provide a much better faceseal than the filtering facepieces.

G. OSHA Asbestos Standard

In June 1972, OSHA promulgated a standard on occupational exposure to asbestos that established an 8-hour time-weighted average (TWA) permissible exposure limit (PEL) of 5 fibers per centimeter (cc) of air, and the limit was lowered to 2 fibers/cc in 1976. The standard permitted the use of reusable or single use particulate respirators for protection against asbestos dust for a concentration of up to 10 times OSHA PEL. In October 1975, OSHA published a notice of proposed rulemaking to revise the asbestos standard because OSHA believed that "sufficient medical and scientific evidence has been accumulated to warrant the designation of asbestos as a human carcinogen." The proposal would have reduced the 8-hour TWA to 0.5 fiber/cc. A hearing was held in 1984. In June 1986, OSHA published the final rule, which further reduced the 8-hour asbestos TWA limit to 0.2 fiber/cc [21].

H. Manufacturer's Responsibility

At the revision of 30 FR 11 public meeting, Mr. Einar Horne, a high level 3M official, made a presentation [22]. He stated *"If the personal protective equipment manufacturer takes the profits and gains from the sale of a personal protective device, he should he liable. In the case of a major defect being discovered in the user's product, it is the manufacturer's responsibility, not NIOSH's. The responsible manufacturer must locate and inform their customers of the problem*." *"It is possible that the existing NIOSH testing does more harm than good based on the fact that the tests have little, if any, correlation to actual field conditions." "Existing NIOSH approvals are marketing device having little or no true merit." "In the case of major defect being discovered in the user's product, it is the manufacturer's responsibility, not NIOSH's. The responsible manufacturer must locate and inform their customers of the problem."*

Section 11.2-1 of 30 CFR 11 has the following requirements: "*In order to insure the maximum amount of protection, approved respirators shall be selected, fitted, used, and maintained in accordance with then provisions of the American National Standards Practices for Respiratory Protection, Z 88.2".* The regulation has not specified the year of the ANSI Z88.2 standard. Since the respirator testing and certification regulations apply to the manufacturer, it means that the manufacturers must provide this information to the respirator users. The following requirements specified in the ANSI Z88.2-1980 standard are related to Section 11.2-1 of 30 CFR 11:

6.9 Respirator Characteristics, Capabilities, and Limitations. The physical characteristics, the functional

capabilities, and the performance limitations of the various types of respirators shall be considered in selecting a respirator.

6.14 Face Dimensions and Facepiece Sizes. The wide range of face dimensions requires more than a single size of respirator facepiece to provide a proper fit to all respirator users. Therefore, respirator facepieces of more than one size shall be available in any respirator-selection program involving respirators equipped with facepieces.

A6. Quantitative fit test. A test aerosol that has a diameter of 0.5 to 0.7 micrometer is used for performing fit test. The test only evaluates the leak around the faceseal. However, the 3M 8710 filter would allow significant leakage of the test aerosol to fail the test.

A7.1 Irritant or Odorous Test Agent. The person wearing a respirator is exposed to an irritant smoke, odorous isoamyl acetate vapor, or other suitable test agent easily detectable by irritation, odor, or taste (an air-purifying respirator must be equipped with the appropriate air-purifying element). If the respirator wearer is unable to detect the penetration of the test agent into the respirator, it can be reasonably assured that the seal of the respirator to the wearer is satisfactory.

A7.2 Negative-Pressure Sealing Test. A negative-air-pressure respirator scaling test can be used on air-purifying respirators equipped with tight-fitting respiratory-inlet coverings and on atmosphere-supplying respirators equipped with tight-fitting respiratory-inlet coverings and breathing tubes which ***can be*** *squeezed or blocked at the inlet to prevent the passage of air.* ***This test may be difficult or impossible to carry out on valveless respirators.***

A7.3 Positive-Pressure Sealing Test. A positive-air-pressure test can be used on respirators equipped with tight-fitting respiratory-inlet coverings which contain both inhalation and exhalation valves. ***This test may be difficult or impossible to carry out on valveless respirators****. The exhalation valve or breathing tube, or both, is closed off and then the wearer exhales gently.*

As a responsible respirator manufacturer, 3M failed to provide these requirements to the respirator users, such as the plaintiff and his employer.

At the 1988 7th International Pneumoconiosis Conference Respiratory protection equipment session on performance standards in developing countries, D. P. Wilmes from the 3M company made a presentation [23]. He stated "*Faces are highly variable. They come in many sizes and shapes and contain highly variable features. Generally, no one model of respirator will fit all faces. No one to date has been successful predicting the fit of a respirator on an individual using any scheme. Yet fit is a very important aspect in respiratory protection*" He failed to mention in his presentation that the 3M 8710 only has one size facepiece.

In 1980, OSHA issued a field directive, OSHA 300-9, requiring fit testing. The directive provided the following instructions to the OSHA Compliance Officers:

1. Respirators must be fit-tested.

2. A "test atmosphere" must be applied to assess the quality of fit.

3. The fit-test must be applied to each and every employee required to wear a respirator.

4. The fit-testing requirement applies to all negative pressure respirators including single-use respirators.

5. The "test atmosphere" must be applied using recognized qualitative fit-testing procedures utilizing iso-amyl acetate, irritant smoke, etc.; or quantitative fit testing using DOP, NaCl, etc.

3M has not included the OSHA fit testing requirements in the 3M 8710 user instructions.

On August 1980, NIOSH sent a notice to 3M [24]. NIOSH stated that there is no asbestos exposure level below which clinical effects do not occur, significant disease can occur following very short (1 day to three months) exposure periods; worker exposure to asbestos must be controlled to the maximum extent possible; and human occupation exposure to all commercial asbestos fiber type have been associated with high rate of lung cancer and mesothelioma. NIOSH expressed concerns that the use of dust, fume, and mist filter respirators may not have the filter media ability to effectively remove the carcinogenic substances during the entire period of use. NIOSH also had concerns about the questionable face fit of at least some dust/mist, or dust, fume, and mist respirators, particularly the single use type. Excessive leakage of a substance such as asbestos into the respirator due to either ineffective filtration or leakage around a poor seal is unacceptable and presents a potentially serious hazard to the wearer. NIOSH's letter was a follow up to a July 18, 1980 letter that granted an extension of approval, and did not allow using the 3M 8710 for protection against asbestos containing dusts and mists.

In 1981, Norton Company, a major respirator manufacturer, sent a notice to their customers. It indicated that the company no longer recommended the use of non-high-efficiency filters for protection against asbestos.[25]

3M was aware of the Norton and NIOSH notices. However, 3M still sold the 8710 respirator for protecting against asbestos fibers until the revised OSHA asbestos standard was published in 1986. It disallowed the use of disposable respirators, such as the 3M 8710, for protection against asbestos fibers. 3M requested NIOSH to remove the asbestos approval from the 8710 for domestic use. However, 3M still maintained the asbestos approval for the 3M 8710 for sale outside the United States. It appears that 3M places profit over human health.

As a responsible manufacturer, 3M shipped to the distributors the 8710 respirator that failed the quality assurance test. When NIOSH informed 3M that the 8710 was not acceptable for protection against asbestos dust or mist, 3M still sold the 8710 to customers. 3M failed to disclose that the 8710 could be fit tested prior

1983, and that the dust/mist filter equipped 8710 does not provide effective protection against submicron particles. Also, the 3M developed fit check procedure for the 8710 was ineffective.

The 3M developed sodium saccharin qualitative fit testing method was accepted by OSHA in November 1982. None of the fit testing methods specified in the ANSI Z88.2-1980 standard is acceptable for the 3M 8710. 3M knowingly sold the 3M 8710 to the users without disclosing that the 8710 could not be fit tested until 1983 or later. However, 3M failed to provide this requirement in the 3M 8710 user instructions to the respirator users.

Conclusions

3M has provided misrepresentations or failed to provide warnings on the following defects:

1. These respirators were tested against submicron silica dust and it provided effective protection against respirable particles. However, the silica dust has a size of 1.8 microns.
2. The dust/mist filter can only be effective when a cake of dust is formed on the filter. Before the cake is formed, the wearer would constantly inhale the respirable asbestos fiber through the filter and the faceseal.
3. Asbestos fibers may penetrate the faceseal. There is no faceseal penetration test for respirator certification.
4. Not able to perform effective fit testing.
5. One size facepiece would not fit all users.
6. Effective pressure sealing test (fit check) cannot be performed.
7. The filtering facepiece respirator does not provide a tight faceseal on the face; it allows penetration of respirable asbestos dust.

Neither the plaintiff nor his employer has received these warnings. The 3M 8710 respirator was not tested against respirable particles such as asbestos fibers, during the certification test. The filter of the 3M 8710 respirator would allow significant penetration of respirable particles. The 3M 8710 respirator has only one size, so it only provides an adequate fit to a limited number of wearers. However, 3M 8710 respirator wearers were not informed that they should select a respirator having multiple sizes. Prior to OSHA accepting the 3M developed sodium saccharin qualitative fit testing method, the 3M 8710 could not be fit tested until 1983. The 3M 8710 could only be fit tested with particles that were less likely to penetrate the respirator faceseal. The U. S. Court of Appeals has ruled that the 8710 respirator wearer was not able to perform an effective fit check prior to entry into a hazardous atmosphere.

Section 56/57.5005 Respiratory Protection of the MSHA Program Policy Manual (VOLUME IV) states "*Respirator selection directly affects the efficiency of the respirator. Respirators are designed to protect wearers from inhalation of hazardous atmospheres. There are many different types of respirators but each is limited in protection and application. A respirator can only protect against atmospheres for which it is designed. Without proper selection a serious health hazard may occur. A serious hazard may also occur if the respirator, even though properly selected, is not fitted as required by the standard. Fit testing is essential in order to assign the correct model and size respirator to a miner. Otherwise, it is likely that the respirator will leak and the miner will be overexposed to the toxic substance*."

The MSHA statements should also apply to workers under OSHA's jurisdiction. 3M was aware of the

8710 respirator's limitations, and that it may not have been suitable for protecting against asbestos fibers. However, 3M still promoted this respirator for occupational use.

Asbestos dust is not detectable by the respirator wearer, and the plaintiff was not aware that he was inhaling the dangerous dust into his lungs. Based on the deficiencies noted, the 3M 8710 respirator was defective for industry use. These defects were not apparent to the industrial workers, or to the plaintiff. The defects caused the plaintiff to suffer substantial exposure to asbestos, which substantially increased his risk of contracting an asbestos related disease, and constitute a substantial factor in the development of the fatal disease.

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